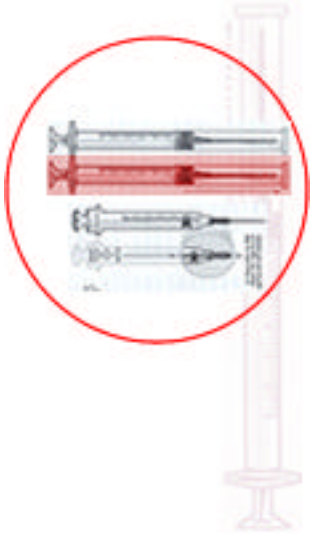
NIOSH recommends that health care facilities use safer medical devices to protect workers from needlestick and other sharps injuries. Since the passage of the Needlestick Safety and Prevention Act in 2000 and the subsequent revision of the OSHA Bloodborne Pathogen Standard, all health care facilities are required to use safer medical devices.

SAFER MEDICAL DEVICE IMPLEMENTATION IN HEALTH CARE FACILITIES

SHARING LESSONS LEARNED

NIOSH has asked a small number of health care facilities to share their experiences on how they implemented safer medical devices in their settings. These facilities have agreed to describe how each step was accomplished, and also to discuss the barriers they encountered and how they were resolved, and most importantly, lessons learned.



Phase 4: Evaluate Safer Medical Device(s)

Description of Facility

Our hospital is licensed for approximately 300 beds and serves a diverse patient population ranging from neonates to geriatric patients. There are three critical care units including a level III+ neonatal intensive care unit (NICU). The hospital has one of the highest volumes of surgical cases in the region. Surgical services are provided through an in-patient general surgical center and two ambulatory surgical centers. A sub-acute unit, a medical-psychiatric unit, and a dialysis unit are on site. Specialty services include Neonatology, Ophthalmology, an Endoscopy Center, and a comprehensive Oncology Service. The community recognizes the OB Service as a center of excellence. Outpatient diagnostic and treatment facilities include a Cardiac Catheter Laboratory, Radiation Oncology, Diabetes and Nutrition Center, and a Wound Care Center. A community health center offers 7 day a week urgent care services to inner-city residents, in addition to providing care in a number of specialties including pediatrics, and HIV care.

Describe the safer medical device(s) evaluated in your facility by providing the following information:

Our hospital decided to evaluate a safety engineered scalpel. The scalpel has a retractable blade that is designed to prevent sharps injuries. Typically, these injuries occur when scalpels are passed between members of the surgical team, when the scalpel is in a temporary location (ie: Mayo stand), or prior to disposal. The device was evaluated in two different surgical settings: the in-patient operating rooms and an ambulatory surgical center.

Which staff used the device (e.g., nurses, phlebotomists, dentists).

Staff who used the device included surgeons, nurses, and surgical technicians. Although nursing staff and surgical technicians do not perform surgery, they are frequently at risk for exposure because they are responsible for managing the flow of surgical instruments into and out of the operative field of the procedure. Therefore, they are often involved in handing or passing sharps to a physician or other surgical assistant.

Describe the staff training on the device.

Staff training was provided through a number of different methods. On site training was conducted by a product representative. Several senior level nurses (RN clinical leaders) charged with coordinating the pilot study provided training to staff who could not attend the sessions held by the representative. Educational brochures provided by the device manufacturer were utilized as part of the training process. Special emphasis was placed on the mechanism for activating the blade retraction system. Infection Control also presented a brief presentation showing that sharps injuries in the OR accounted for more than 50% of all sharps injuries throughout the hospital.

Describe the *process* used to evaluate the device and the timeframe for this process

The safety scalpel was piloted in two different surgical settings. There was a one-week clinical trial conducted for the in-patient operating rooms and a one-week clinical trial conducted in an ambulatory care center. Data about the scope and magnitude of sharps injuries in the OR was also shared with medical staff, nurses, and technicians. Provisions of the *Needlestick Prevention Act of 1999* and the *2001 Revised Bloodborne Pathogen Standard* which stipulate mandatory

evaluations of sharps injury protection devices were reviewed with the staff, so they would have a better understanding of the regulatory environment.

A product evaluation form was distributed by the OR nurses who were assisting the study coordinator (See Attachment 1). Announcement of educational sessions and the timeframe for the trials were prominently posted in employee lounges and in other strategic areas. The RN clinical leaders were charged with encouraging both employees and medical staff to complete the evaluation form.

During the trial, participants were asked to document any difficulties they encountered with the device with respect to patient safety as well the product's safety features. At the end of the clinical trial, evaluation forms were completed and returned to the study coordinator for analysis. The most important question on the form was "*Do you feel this product should be implemented for use*?" A total of fifty-one (51) evaluation forms were distributed. Forty (40) were completed and returned.

Describe the criteria and measures used in the device evaluation and how it was collected and analyzed.

We asked staff participating in the trial to consider the following characteristics: Ease of safety feature activation, quality of the retraction mechanism, the weight of the scalpel compared to a traditional scalpel, the availability of particular sizes or shape of the surgical blade as required for a particular procedure, sharpness of the blade, and whether there was a potential for patients to be harmed. A standard product evaluation form was used as a questionnaire. A more detailed form (See Attachment 2) had been adopted from the Training for Development of Innovative Control Technologies (TDICT) Project's web site (http://www.tdict.org/criteria.html), but OR staff believed the data collection burden was too great and recommended using the standard form used by our Value Analysis Committee. Users were instructed and encouraged to provide comments on the form whenever the safety device was not optimal or equivalent to the traditional scalpel.

After the forms were collected, the number of positive and negative responses to the final question, "*Do you feel this product should be implemented for use*" were tabulated. Twenty-six (26) evaluations were not in favor of implementation, twelve (12) evaluations supported implementation, and two (2) evaluations were neutral.

Did the evaluation process that you used give you sufficient information (data) to be able to determine the effectiveness of the device and whether to continue or discontinue its use?

Fifty-one (51) product evaluation survey forms were distributed. Forty (40) surveys were completed and submitted to the study coordinator. Our return rates was 78%, so we had a good response and believe that the comments submitted were an accurate reflection of the surgical staff. The majority of evaluators did not favor implementation of the safety scalpel. The major objection was the blade handle was not designed ergonomically. Evaluators' comments included the following:

"Scalpel is not heavy enough for orthopedic use, bulky or clumsy to handle, slippery, required a greater time commitment and slowed surgical procedures which impaired patient care, blade was not sharp enough, selection of blade sizes not adequate, unable to create deep, narrow incisions, handle too short, will not prevent most sharps injuries, product is cumbersome to use"

Did you determine whether or not the device was being used as planned during this phase? If so, how? What problems, if any, did you have in getting employees to use the device? How did you resolve those problems?

We determined through direct observation of surgical procedures whether the device was being used during the trial. The safety scalpel was well received by many operating rooms nurses and technicians. However, resistance was encountered among surgeons, as the safety scalpel represented a change in their technique with respect to the workflow in the surgical setting. Issues identified early during the trial included the increased time needed for activating the retracting mechanism and the weight of the scalpel. Because the handle of the safety scalpel is disposable and made from plastic, the device is considerably lighter than the steel handles of traditional scalpels. These problems could not be resolved during the trial.

What lessons were learned during the process of evaluating safer medical devices? Describe the difficulties encountered and how problems were resolved.

The major lesson we learned was not to attempt a clinical trial with a device that hasn't had at least one success story at another healthcare facility. Even though we had clearly identified a problem with scalpel injuries, there was no evidence in the literature that safety scalpels are an effective intervention. We also could not prospectively identify a product that was acceptable to surgeons and other surgical staff. The other major lesson learned was safety engineered sharps are accepted by surgeons only if they are ergonomically designed and equivalent to traditional devices with regards to clinical efficacy.

What would you do differently if you were to begin this process again?

We would allow the medical staff more time handling and using a particular safety device prior to selecting one for clinical trial. We would also require use of the more detailed evaluation form.

What advice would you offer a similar facility that is just starting this process?

New and better safety scalpels which more closely resemble traditional scalpels are under development and will be marketed before the end of 2004. It is our understanding they will be similar in weight to traditional non-safety scalpels and more ergonomic. We recommend facilities consider these safety scalpels as they become available.

What role did the sharps injury prevention team play in this process?

The sharps injury prevention team did not play a significant role during the pilot study. Once the pattern of injury in the surgical setting was established and a device was selected to trial, the issue was referred to an OR team charged with developing a plan for decreasing sharps injuries. The sharps injury team coordinator assisted the OR team by analyzing data from the evaluation.

Staff Hours and Other Cost Items

Staff Hours:

Type of Staff	Hours Spent on Phase 4
Management	14
Administrative	3
Front-line	68
Total	85

Other, non-labor items:

Item
1. Copying costs

VALUE ANALYSIS PRODUCT EVALUATION REPORT

DATE: _____ CONTROL NUMBER: _____

ITEM TO BE EVALUATED: _____

COMPANY/MANUFACTURER: _____

THIS PRODUCT HAS BEEN APPROVED BY THE VALUE ANALYSIS COMMITTEE

FOR A: _____ EVALUATION EFFECTIVE: _____

PLEASE COMPLETE ALL EVALUATION DATA AND RETURN TO COORDINATOR:

NAME: _____ EXTENSION: _____

TO BE COMPLETED BY EVALUATING PHYSICIAN / CLINICIAN

PRODUCT FOR PURPOSE IS: ☐ EXCELLENT ☐ GOOD ☐ FAIR ☐ POOR

EASE OF USE: ☐ EXCELLENT ☐ GOOD ☐ FAIR ☐ POOR

QUALITY OF PATIENT CARE: ☐ IMPROVED ☐ IMPAIRED ☐ LITTLE EFFECT

TIME COMMITMENT: ☐ TIME SAVED ☐ ADD'L TIME REQ'D ☐ N/A

IF SIMILAR PRODUCT IS BEING USED, COMPLETE THE FOLLOWING:

COMPARED TO CURRENT PRODUCT, THIS IS:

☐ SUPERIOR ☐ COMPARABLE ☐ INFERIOR

SPECIFIC ADVANTAGES/DISADVANTAGES OF THE PRODUCT ARE: _____

_____

DO YOU FEEL THIS PRODUCT SHOULD BE IMPLEMENTED FOR USE? ☐ YES ☐ NO

IF NO, WHY NOT? _____

_____

EVALUATED BY: _____ DATE: _____

TO BE COMPLETED BY EVALUATING STAFF

EASE OF HANDLING: ☐ EXCELLENT ☐ GOOD ☐ FAIR ☐ POOR

PACKAGING: ☐ EXCELLENT ☐ GOOD ☐ FAIR ☐ POOR

LABELING/INSTRUCTIONS: ☐ EXCELLENT ☐ GOOD ☐ FAIR ☐ POOR

COMPARED TO CURRENT PRODUCT, THIS IS:

☐ SUPERIOR ☐ COMPARABLE ☐ INFERIOR

SPECIFIC ADVANTAGES/DISADVANTAGES OF THE PRODUCT ARE: _____

_____

DO YOU FEEL THIS PRODUCT SHOULD BE IMPLEMENTED FOR USE? ☐ YES ☐ NO

IF NO, WHY NOT? _____

_____

EVALUATED BY: _____ DATE: September 22, 2003

ADDITIONAL COMMENTS? PLEASE USE REVERSE OF THIS FORM

SAFETY SCALPEL EVALUATION FORM

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

DURING USE:	**True**	**False**
1. The safety feature can be activated using a one-handed technique.	☐	☐
2. The safety feature **does not** interfere with the optimal performance of the operative procedure.	☐	☐
3. Use of this product requires you to use the safety feature.	☐	☐
4. This product does not require more time to use than a non-safety device	☐	☐
5. The safety feature works well with a wide variety of hand sizes.	☐	☐
6. The device is easy to handle while wearing gloves.	☐	☐
7. The scalpel blade is as sharp as a traditional blade.	☐	☐
8. The weight of the device is acceptable.	☐	☐
9. This device does not compromise patient safety,	☐	☐
10.This device provides a better alternative to traditional scalpels.	☐	☐
AFTER USE:		
11. There is a clear and unmistakeable change (audible or visible) that occurs when the safety feature is activated.	☐	☐
12.The safety feature operates reliably.	☐	☐
13. The exposed sharp is permanently blunted or covered after use and prior to disposal.	☐	☐
TRAINING:		
15. The user does not need extensive training for correct operation.	☐	☐
16. The design of the device suggests proper use.	☐	☐
17. It is not easy to skip a crucial step in proper use of the device.	☐	☐

Reference:
Safety Syringe Evaluation Form
© June1993. revised August 1998
Training for Development of Innovative Control Technology Project (http://www.tdict.org/criteria.html)

*The Safety Syringe Evaluation Form was modified for a trial of safety scalpels.